REMARKS

An Office Action was mailed in the above-captioned application on January 14, 2009. Claims 1-22 and 29-31 were pending in the application. Claims 1-22 and 29-31 were subject to restriction/election requirement. This Response to Restriction Requirement and Amendment document is submitted in response to the Office Action. Claims 29-31 have been withdrawn. New Claim 32 has been added and is believed to be encompassed by Group I of the Examiner's Restriction Requirement. The Specification has been amended for clarification. Applicants believe that no new matter has been added.

Restriction Requirement under 35 U.S.C. §§ 121 and 372

A restriction requirement was made to pending Claims 1-22 and 29-31. The claims were placed into two groups:

Group I, Claims 1-22, drawn to a liposomal formulation;
Group II, Claims 29-31, drawn to a method of preparing liposomal formulations.

Applicant hereby provisionally elects to prosecute the invention of the Examiner's Group I, Claims 1-22, with traverse.

In addition, a species election for Group I has been required by the Examiner. The Applicant is required to elect a single compound for each of the following: hydrophilic agent, neutral saturated phospholipid and charged saturated lipid. The Applicant hereby elects:

1) hydrophilic agent: 5'fluorouracil (encompassed by Claim 11)
2) neutral saturated phospholipid: DSPC (encompassed by Claim 3)
3) charged saturated lipid: DSPG (encompassed by Claim 5)

As stated in MPEP § 803, "[t]here are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent ... or distinct as claimed...; and (B) There must be a serious burden on the examiner if restriction is required....".

Applicants respectfully disagree that an examination or search of the inventions of Groups I and II would constitute a serious undue burden on the Examiner. The Office action

reasons that the inventions in Group I and II are drawn to multiple methods and multiple products.

Applicants submit that a search for a liposomal formulation of Group I, would overlap with a search for the preparation of a liposomal formulation of Group II. In addition, insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria are set forth in MPEP § 803.02. If the members of the Markush group are sufficiently few in number (as in the case in the pending claims) or so closely related that a search and examination of the entire claim can be made without serious burden, the Examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the Examiner will not require restriction.

Thus, a search of the invention of Group I necessarily includes a search of the invention of Group II. These searches, therefore, appear to be co-extensive and should not constitute a serious undue burden on the Examiner. Applicants therefore submit that restriction among Groups I and II is improper and respectfully requests examination of Claims 1-22 and 29-31.

Closing Remarks

If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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